

DOCKET NO. 208858US0PCT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: David LEWIS et al

SERIAL NO.: 09/831,888

GAU: 3761

FILED: July 19, 2001

EXAMINER: MITCHELL, T.K.

FOR: PRESSURISED METERED DOSE INHALERS (MDI)

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants wish to disclose the following information.

**REFERENCES**

- ☒ The Applicants wish to make of record the references listed on the attached Form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR §1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached Form PTO-1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

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180.00 DP

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

  
Stephen G. Baxter

Registration No. 32,884

Customer Number

**22850**

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)

JAN 0 6 2005

SHEET 1 OF 4

Form PTO 1449  
(Modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO.  
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LIST OF REFERENCES CITED BY APPLICANT

APPLICANT  
David LEWIS et al

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July 19, 2001

GROUP  
3761

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	2003/0190287 A1	10/09/03	David LEWIS et al			
	AB	2003/0206870 A1	11/06/03	David LEWIS et al			
	AC	6,045,778	04/04/00	Paul Donald JAGER et al			
	AD	5,676,930	10/14/97	Paul D. JAGER			
	AE	6,413,496	07/02/02	Michael GOODMAN et al			
	AF	5,642,728	07/01/97	Jan ANDERSSON et al			
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	AH	5,605,674	02/25/97	Tarlochan S. PUREWAL et al			
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	AJ	6,241,969	06/05/01	Zahir SAIDI et al			
	AK	5,891,419	04/06/99	Anthony J. CUTIE			
	AL	5,192,528	03/09/93	R. RADHAKRISHNAN et al			
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	AN	6,253,762	07/03/01	Ignatius Loy BRITTO			

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		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AO	WO 98/34595	08/13/98	WIPO		XXX
	AP	0 372 777	06/13/90	EPO		
	AQ	0 911 048	04/28/99	EPO		
	AR	WO 99/12596	03/18/99	WIPO		
	AS	WO 92/20391	11/26/92	WIPO		
	AT	WO 98/03533	01/29/98	WIPO		
	AU	1 525 181	09/20/78	GB		
	AV	WO 96/19969	07/04/96	WIPO		XXX

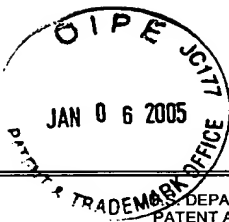
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	S.S. DAVIS, "Physico-Chemical Studies on Aerosol Solutions For Drug Delivery I. Water-Propylene Glycol Systems", <u>International Journal of Pharmaceutics</u> , 1, 1978, pp. 71-83.	
	AX	L. Harrison et al, "Twenty-eight-day Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in Healthy Subjects", <u>J. Pharm. Pharmacol.</u> , 1996, Vol. 48, pp. 596-600.	
	AY	P. Hoet et al, "Epidemic of liver disease caused by hydrochlorofluorocarbons used as ozone-sparing substitutes of chlorofluorocarbons", <u>The Lancet</u> , 1997, Vol. 350, pp. 556-559.	
	AZ	J. Daly, Jr., "Properties and toxicology of CFC alternatives", <u>Aerosol Age</u> , February 1990, pp. 26-27, 40, 56 and 57.	<input type="checkbox"/> Additional References sheet(s) attached

Examiner

Date Considered

\*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	AA	4,499,108	02/12/85	Joel A. SEQUEIRA et al			
	AB	5,955,058	09/21/99	Paul Donald JAGER et al			
	AC	6,150,418	11/21/00	Dieter HOCHRAINER et al			
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
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	AO	WO 94/14490	07/07/94	WIPO		XXX
	AP	WO 99/64014	12/16/99	WIPO		
	AQ	WO 00/30608	06/02/00	WIPO		
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	AU	0 653 204	05/17/95	EPO		
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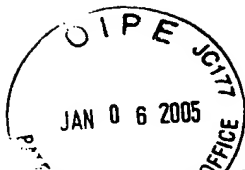
## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	D. Strobach, "Alternatives to CFCs" Part II, <u>Aerosol Age</u> , July 1988, pp. 32-33, 42 and 43				
	AX	Tsi-Zong Tzou et al, "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", <u>Journal of Pharmaceutical Sciences</u> , 1997, Vol. 86, No. 12, pp. 1352-1357.				
	AY	M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", <u>Journal of Aerosol Medicine</u> , 1991, Vol. 4, No. 3, pp. 181-187.				
	AZ	I. P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", <u>The Pharmaceutical Journal</u> , 1997, Vol. 259, pp. 896-898.			<input type="checkbox"/> Additional References sheet(s) attached	

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	AO	WO 91/11173	08/08/91	WIPO		
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	AQ	WO 94/21228	09/29/94	WIPO		
	AR	WO 96/18384	06/20/96	WIPO		
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	AV	WO 00/07567	02/17/00	WIPO		XXX

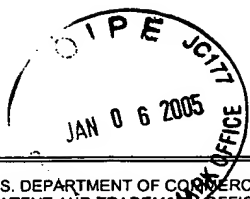
## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	D. Tiwari et al, "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, <u>Drug Development and Industrial Pharmacy</u> , 1998, Vol. 24, No. 4, pp. 345-352.				
	AX	<u>Handbook of Pharmaceutical Excipients</u> , 3rd Ed., Kibbe Editor, pp. 7-9, 220-222, 234-235 and 560-561.				
	AY	L. I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", <u>Biopharmaceutics &amp; Drug Disposition</u> , 1997, Vol. 18, No. 7, pp. 635-643.				
	AZ	Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", <u>Respiratory Drug Delivery V</u> , 1996, pp. 133-144.				<input type="checkbox"/> Additional References sheet(s) attached

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	AR	WO 00/23065	04/27/00	WIPO		XXX
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	AT					
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